

Notice of Allowability

Application No.

10/736,742

Examiner

Janet L. Coppins

Applicant(s)

LEBAN ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' Amendment of October 30, 2007.
2. ☒ The allowed claim(s) is/are 1-5,8 and 9.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

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DETAILED ACTION

1. Claims 1-5, 8 and 9 are now pending in the instant application.

Response to Amendment

2. Applicants' Amendment of October 30, 2007 has been reviewed by the Examiner and entered in the file. Accordingly, claims 1, 5 and 8 have been amended, and claims 6 and 7 have been cancelled.

Claim Rejections - 35 USC § 112

3. Claims 5 and 6 previously rejected under 35 U.S.C. 112, first paragraph, as not being fully enabled. In view of Applicants' amendments to insert specific diseases that are treated by inhibiting dihydroorotate dehydrogenase, the rejection has been overcome and is withdrawn.
4. Claim 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have cancelled claim 7, therefore the rejection is withdrawn.
5. Claim 8 previously rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps. In view of Applicants' amendment to include steps defining the process of preparation, the rejection is overcome and is withdrawn.

Allowable Subject Matter

6. Claims 1-5, 8 and 9, now in amended form, appear allowable over the prior art.

Reasons for Allowance

7. In view of Applicants' amendatory changes and cancellations, claims 1-5, 8 and 9 are allowable, as newly renumbered claims 1-7.
8. The following is an examiner's statement of reasons for allowance:

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This invention relates to novel substituted 5-membered disubstituted heteroaromatic compounds of formula (II), their pharmaceutical compositions, methods of use, and processes of preparation. The allowable compounds are limited to compounds according to general formula (II) of claim 1. Certain 5-membered heteroaryl compounds are known in the art, however the aspect of preparing the instant claimed compounds with DHODH inhibitory activity, for treating diseases wherein inhibition of pyrimidine metabolism is beneficial, is novel and unobvious. The instant compounds were tested for their inhibitory effects on DHODH and the results demonstrate the compounds' efficacy for inhibiting the production of human DHODH, which makes them useful for treating certain immunomodulatory and anti-inflammatory diseases such as rheumatism, fibrosis, asthma, and psoriasis, etc. After a thorough search, the closest of prior art, U.S. Pat. No. 5,258,357 to Muenster et al. was found to teach similar thiophene- or furan-carboxamides. However the '357 patent fails to teach or render obvious the same instant claimed compounds according to formula (II), and does not fairly suggest methods of using the instant claimed compounds to inhibit DHODH for treating rheumatism, rhinitis, asthma, etc.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Coppins
January 5, 2008

Kamal A. Saeed, PhD.
Primary Examiner, Art Unit 1626

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Telephone Inquiry

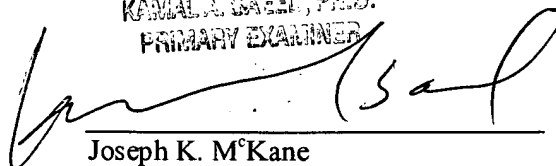
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Janet L. Coppins
April 7, 2007

KAMALA SATER, Ph.D.
PRIMARY EXAMINER



Joseph K. McKane
SPE, Art Unit 1626